

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231*[Handwritten signature]*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/308,830 08/04/99 SCHLIEVERT

P 600-346USWO

023552  
MERCHANT & GOULD  
P O BOX 2903  
MINNEAPOLIS MN 55402-0903

HM22/0601

EXAMINER

ZEMAN, R	
ART UNIT	PAPER NUMBER

1645  
DATE MAILED:

06/01/01

*20*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/308,830</b>	Applicant(s) <b>Schlievert et al</b>
	Examiner <b>Robert A. Zeman</b>	Art Unit <b>1645</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on Mar 2, 2001
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 30-101 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 30-101 are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

Art Unit: 1645

## **DETAILED ACTION**

### *Continued Prosecution Application*

The request filed on 3-2-2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/308,830 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed on 3-2-2001 is acknowledged. Claims 1, 3-9, 12-14, and 17-29 have been canceled. Claims 30-101 have been added and are currently pending.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 30-45, 47, 50-72, 74, 77-86, 88, 91-97 and 99, drawn to SPE-A mutants, classified in class 530, subclass 350.
- II. Claims 46, 73, 87 and 98, drawn to vaccines, classified in class 424, subclass 190.1.
- III. Claims 48, 75, 89 and 100, drawn to methods of protecting animal from effects of SPE-A, classified in class 424, subclass 244.1.
- IV. Claims 49, 76, 90 and 101, drawn to methods of reducing symptoms associated with toxic shock, classified in class 424, subclass 282.1.
- Join*

Art Unit: 1645

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not have the added limitation of having to induce a protective immunity against the effects of SPE-A. Therefore the subcombination has separate utility such as use as a protective agent (vaccine).

Invention I is related to Inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the SPE-A mutants of Invention I can be for antibody purification.

Invention II is related to Inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

Art Unit: 1645

product (MPEP § 806.05(h)). In the instant case the vaccine compositions of Invention II can be used for antibody purification.

Inventions III and IV are separate and distinct from each other as they are drawn to differing methods having different steps and leading to differing results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.



DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman

May 31, 2001